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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,044	02/26/1997	MARGARET BYWATER	1614-178P	1463

2292 7590 03/27/2002  
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EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/776,044	BYWATER ET AL.
	Examiner Natalie A. Davis	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 December 2001.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10, 14 and 15 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-10, 14 and 15 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

**The Group Art Unit examiner** of the application **has been changed**. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Dr. Natalie A. Davis**.

Applicant's amendment filed 26 January 2001 (Paper No: 26) is acknowledged. Accordingly, claims 1, 3 14, and 15 are amended. Claims 1-10 and 14-15 are pending.

#### ***Response to Arguments***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112 2<sup>nd</sup> Withdrawn***

1. Rejection of claims 1-10 and 14-15 under 35 U.S.C.112, second paragraph is withdrawn in view of amendments.

#### ***Claim Rejections - 35 USC § 112 1<sup>st</sup> Maintained***

2. Rejection of claim 3 under 35 U.S.C.112, first paragraph is maintained for reasons indicated in the previous office action. The traversal is on the grounds that the specification discloses that mutations in p53 give rise to missense mutations, transcriptional stop signals, truncated proteins, frameshift mutations, and mutations, which are more detrimental to patients as those which affect binding or transactivation. This is not found to be persuasive because without guidance or exemplification, one of ordinary skill in the art would not know which type of mutation in conserved region II and V would give rise to a affect binding or transactivation mutation.

#### ***Claim Rejections - 35 USC § 102 Withdrawn***

3. Rejection of claim 15 over Thorlacius, et al. (1993) under 35 U.S.C. 102(b) is withdrawn in view of amendments.

#### ***Claim Rejections - 35 USC § 103 Withdrawn***

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4. Rejection of claims 1, 2, 4-7, and 14 over Hedrum, et al. in view of Elledge, et al, and Callahan under 35 U.S.C. 103(a) is withdrawn in view of arguments.

***Claim Rejections - 35 USC § 102 Maintained***

5. Rejection of claim 15 over Vogelstein, et al. under 35 U.S.C. 102(e) is maintained for reasons set forth in the previous office action. The traversal is on the grounds that Vogelstein teaches sequencing all or part of the p53 gene. Applicant's arguments have been considered but are not persuasive because Vogelstein teaches sequencing all of the p53 gene, it is inherent that "part" of the gene that is sequenced encompasses exons 2-11. *maintain*

***Claim Rejections - 35 USC § 103 Maintained***

6. Rejection of claims 1, 2, 4-10, and 14 over Vogelstein, et al. in view of Elledge, et al, and Callahan under 35 U.S.C. 103(a) is maintained for reasons set forth in the previous office action. The traversal is on the grounds that no reference teaches a method of prognostication by sequencing exons 2-11 of p52. Applicant's arguments have been considered but are not persuasive because as indicated above it would be reasonable to conclude that Vogelstein sequences exons 2-11 since the reference teaches sequencing of part of the gene. Furthermore, as indicated in the previous office action Elledge, et al, and Callahan teach the prognostic significance of mutations in p53 and Elledge teach the correlation between nodal status and prognosis. *maintain*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD

March 25, 2002

  
ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600